

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Jean-Luc GIRARDET, et al.

Serial Number: 10/526,249

Filing Date: August 3, 2005

Title: NON-NUCLEOSIDE REVERSE
TRANSCRIPTASE INHIBITORS

Group Art Unit: 1614

Examiner: Ardin H. Marschel

CONFIRMATION NO: 6456

FILED ELECTRONICALLY ON: April 12, 2007

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.97

Sir:

Applicants hereby submit an Information Disclosure Statement along with attached form PTO/SB/08. A copy of each listed publication is submitted, if required, pursuant to 37 CFR §§1.97-1.98, as indicated below.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return the attached form PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

- A. ☒ *37 CFR §1.97(b)*. This Information Disclosure Statement should be considered by the Office because:
- ☐ (1) It is being filed within 3 months of the filing date of a national application and is other than a continued prosecution application under §1.53(d);
-- OR --
 - ☐ (2) It is being filed within 3 months of entry of the national stage as set forth in §1.491 in an international application;
-- OR --
 - ☒ (3) It is being filed before the mailing of a first Office action on the merits;
-- OR --
 - ☐ (4) It is being filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
- B. ☐ *37 CFR §1.97(c)*. Although this Information Disclosure Statement is being filed after the period specified in *37 CFR §1.97(b)*, above, it is filed before the mailing date of the earlier of (1) a final office action under §1.113, (2) a notice of allowance under §1.311, or (3) an action that otherwise closes prosecution on the merits, this Information Disclosure Statement should be considered because it is accompanied by one of:
- ☐ a statement as specified in §1.97(e) provided concurrently herewith;
-- OR --
 - ☐ a fee of \$180.00 as set forth in §1.17(p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- C. ☐ *37 CFR §1.97(d)*. Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under §1.113 or (2) a notice of allowance under §1.311, it is being filed before payment of the issue fee and should be considered because it is accompanied by:
- i. a statement as specified in §1.97(e);
-- AND --
 - ii. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.
- D. ☐ *37 CFR §1.97(e)*. Statement.
- ☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(c);
-- AND/OR --
 - ☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(d);
-- AND/OR --
 - ☐ A copy of a dated communication from a foreign patent office clearly showing that the information disclosure statement is being submitted within 3 months of the filing date on the communication is provided in lieu of a statement under 37 C.F.R. § 1.97(e)(1) as provided for under MPEP 609.04(b) V.
- E. ☐ *Statement Under 37 C.F.R. §1.704(d)*. Each item of information contained in the information disclosure statement was first cited in a communication from a foreign patent office in a counterpart application that was received by an individual designated in § 1.56(c) not more than thirty (30) days prior to the filing of this information disclosure statement. This statement is made pursuant to the

requirements of 37 C.F.R. § 1.704(d) to avoid reduction of the period of adjustment of the patent term for Applicant(s) delay.

F. ☒ 37 CFR § 1.98(a)(2). The content of the Information Disclosure Statement is as follows:

☐ Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.

-- OR --

☒ Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08 are NOT enclosed.

-- AND/OR --

☒ Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08 are enclosed in accordance with 37 CFR § 1.98 (a)(2).

-- AND/OR --

☒ Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR § 1.98(a)(2)(iii).

G. ☐ 37 CFR § 1.98(a)(3). The Information Disclosure Statement includes non-English patents and/or references.

☐ Pursuant to 37 CFR § 1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.

☐ Pursuant to MPEP 609(B), an English language copy of a foreign search report is submitted herewith to satisfy the requirement for a concise explanation where non-English language information is cited in the search report.

-- OR --

☐ A concise explanation of the relevance of each patent, publication or other information provided that is not in English is as follows: _____

☐ Pursuant to 37 CFR § 1.98(a)(3)(ii), a copy of a translation, or a portion thereof, of the non-English language reference(s) is provided herewith.

H. ☐ 37 CFR § 1.98(d). Copies of patents, publications and pending U.S. patent applications, or other information specified in 37 C.F.R. § 1.98(a) are not provided herewith because:

☐ Pursuant to 37 CFR § 1.98(d)(1) the information was previously submitted in an Information Disclosure Statement for another application under which this application claims priority for an earlier effective filing date under 35 U.S.C. 120.

Application in which the information was submitted: _____

Information Disclosure Statement(s) filed on: _____

AND

☐ The information disclosure statement submitted in the earlier application complied with paragraphs (a) through (c) of 37 CFR § 1.98.

- I. ☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No. 18545-720.831).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: April 12, 2007

By: 

Robert H. Keamey, Ph.D., J.D.
Reg. No. 50,371

650 Page Mill Road
Palo Alto, CA 94304-1050
(650) 493-9300
Customer No. 021971

Under the paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Complete if Known		
			Application Number	10/526,249	
			Filing Date	August 3, 2005	
			First Named Inventor	Jean-Luc Girardet	
			Art Unit	1614	
			Examiner Name	Ardin H. Marschel	
Sheet	1	Of	4	Attorney Docket Number	18545-720.831

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	US 2002/0026186	02/28/2002	Woloszko et al.	
	2.	US 2003/0027433	02/06/2003	Faur et al.	
	3.	US 2005/0054639 A1	03/10/2005	Simoneau	
	4.	US 2006/0135556	06/22/2006	Girardet et al.	
	5.	US 2006/0270725	11/30/2006	Girardet et al.	
	6.	US 5,939,462	08/17/1999	Connell et al.	
	7.	US 6,197,779	03/06/2001	Andries et al.	
	8.	US 6,245,817	06/12/2001	Connell et al.	
	9.	US 6,414,147	07/02/2002	Currie et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ² - Number ³ - Kind Code ⁴ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁵
	10.	CA 1050531	03/13/1979	Shimizu et al.		
	11.	WO 00/27850	05/18/2000	Haddach et al.		
	12.	WO 02/070470	09/12/2002	Chan		
	13.	WO 03/016306	02/27/2003	Guillemont et al.		
	14.	WO 03/097047	11/27/2003	Ammenn et al.		
	15.	WO 2004/069812	08/19/2004	Heeres et al.		
	16.	WO 2005/028479	03/31/2005	Lewi et al.		

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST 16 if possible. ⁶Applicant is to place a check mark here if English language translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Times will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing the burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FORMS OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Correspondence for Patents, P.O. Box 1468, Alexandria, VA 22313-1468.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Complete if Known		
			Application Number	10/526,249	
			Filing Date	August 3, 2005	
			First Named Inventor	Jean-Luc Girardet	
			Art Unit	1614	
			Examiner Name	Ardin H. Marschel	
Sheet	2	Of	4	Attorney Docket Number	18545-720.831

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	† ²
	17.	AINSWORTH, C. 1,2,4-Triazole. Org. Syn., Coll. 1973; Vol. V: 1070. (4 pages)	
	18.	BADGER, et al. Azaindoles. III. The synthesis of pyrazolo[3,4-b]pyridines and pyrazolo-[3,4-d]pyrimidines. Aust. J. Chem. 1965; 18(8): 1267-71.	
	19.	BERGE, et al. Pharmaceutical salts. J. Pharm. Sci. 1977; 66(1): 1-19.	
	20.	BONTEMS, et al. Guanosine analogues: Synthesis of nucleosides of certain 3-substituted 6-aminopyrazolo[3,4-d]pyrimidin-4(5H)-ones as potential immunotherapeutic agents. J. Med. Chem. 1990; 33(8): 2174-8.	
	21.	CONNOR, et al. Characterization of the functional properties of env genes from long-term survivors of human immunodeficiency virus type 1 infection. J. Virol. 1996; 70(8): 5306-11.	
	22.	HARRINGTON, et al. Direct detection of infectious HIV-1 in blood using a centrifugation-indicator cell assay. J. Virol. Methods. 2000; 88(1): 111-5.	
	23.	IBATA, et al. Formation and reaction of oxazoles: Synthesis of N-substituted 2-(aminomethyl)oxazoles. Bull. Chem. Soc. Jpn. 1989; 62: 618-20.	
	24.	IBATA, et al. The acid catalyzed decomposition of diazo compounds. I. Synthesis of oxazoles in the BF ₃ catalyzed reaction of diazo carbonyl compounds with nitriles. Bull. Chem. Soc. Jpn. 1979; 52: 3597-600.	
	25.	LARSEN, et al. Prodrug forms for the sulfonamide group. I. Evaluation of N-acyl derivatives, N-sulfonylamidines, N-sulfonyliminines and N-sulfonylureas as possible prodrug derivatives. Int. J. Pharm. 1987; 37(1-2): 87-95.	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. † Applicant's unique citation designation number (optional). † See Kind Code of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. † Inter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). † For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. † Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. † Applicant is to place a check mark here if English language translation is attached.

This collection of information is required by 37 CFR 1.91 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22315-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1468, Alexandria, VA 22315-1468.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Use as many sheets as necessary)**Complete if Known**

Sheet	3	Of	4
Application Number	10/526,249		
Filing Date	August 3, 2005		
First Named Inventor	Jean-Luc Girardet		
Art Unit	1614		
Examiner Name	Ardin H. Marschel		
Attorney Docket Number	18545-720.831		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁴
	26.	LEWIS, et al. Pyrazolopyrimidine nucleosides. 13. Synthesis of the novel C-nucleoside 5-amino-3-(β-D-ribofuranosyl)pyrazolo[4,3-d]pyrimidin-7-one, a guanosine analogue related to the nucleoside antibiotic formycin B. J. Am. Chem. Soc. 1988; 104: 1073-7.	
	27.	LIU, et al. An improved synthesis of 9-deazaguanine. Synthetic Communications. 2002; 32(24): 3797-802. (edited by Klaus Kielich).	
	28.	LOPES, et al. Acyloxymethyl as a drug protecting group. Part 6: N-acyloxymethyl- and N-((aminocarbonyloxy)methyl)sulfonamides as prodrugs of agents containing a secondary sulfonamide group. Bioorg. Med. Chem. 2000; 8(4): 707-16.	
	29.	LUDOVICI, et al. Evolution of anti-HIV candidates. Part 3: Diarylpyrimidine (DAPY) analogues. Bioorg. Med. Chem. Lett. 2001; 11(17): 2235-9.	
	30.	OLESEN, P. The use of bioisosteric groups in lead optimization. Current Opinion in Drug Discovery & Development. 2001; 4: 471-78.	
	31.	PATANI, et al. Bioisosterism: A rational approach in drug design. Chem. Rev. 1996; 96(8): 3147-76.	
	32.	PLATT, et al. Effects of CCR5 and CD4 cell surface concentrations on infections by macrophagetropic isolates of human immunodeficiency virus type 1. J. Virol. 1998; 72(4): 2855-64.	
	33.	POPIK, et al. Human immunodeficiency virus type 1 uses lipid raft-coloalized CD4 and chemokine receptors for productive entry into CD4(+) T cells. J. Virol. 2002; 76(10): 4709-22.	
	34.	POSTE, et al. Lipid Vesicles as Carriers for Introducing Biologically Active materials into Cells. Methods Cell Biol. 1976;14: 33-71.	
	35.	ROOS, et al. LuSIV cells: A reporter cell line for the detection and quantitation of a single cycle of HIV and SIV replication. Virology. 2000; 273(2): 307-15.	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of the form with next communication to applicant. *Applicant's unique citation designation number (optional). *See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *Issue Office that issued the document, by the two-letter code (WIPO Standard ST. 3). *For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. *Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. *Applicant is to place a check mark here if English language translation is attached.

The collection of information is required by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing the burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO			Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Application Number	10/526,249	
			Filing Date	August 3, 2005	
			First Named Inventor	Jean-Luc Girardet	
			Art Unit	1614	
			Examiner Name	Ardin H. Marschel	
Sheet	4	Of	4	Attorney Docket Number	18545-720.831

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No.†	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ⁶
	36.	SCOTT, et al. A new route to the imidazole-2-thiones from 2-thiohydantoins. Implications in the study of ergothioneine. Biochem J. 1968; 109(2):209-15.		
	37.	SEELA, et al. Synthesis of 2'-deoxyribofuranosides of 8-aza-7-deazaguanine and related pyrazolo[3,4-d]pyrimidines. Helvetica Chimica Acta. 1986; 69(7): 1602-13.		
	38.	SEELA, et al. The high-anti conformation of 7-halogenated 8-aza-7-deaza-2'-deoxy-guanosines: A study of the influence of modified bases on the sugar structure of nucleosides. Helvetica Chimica Acta. 1999; 82(1): 105-24.		
	39.	TAYLOR, et al. Synthesis of pyrazolo[3,4-d]pyrimidine analogues of the potent antitumor agent N-{4-[2-amino-4(3H)-oxo-7H-pyrrolo[2,3-d]pyrimidin-5-yl]ethyl]benzoyl}-L-glutamic acid (LY231514). Tetrahedron. 1992; 48(37): 8089-100.		
	40.	YOUSSEF, et al. A Facile One-pot Synthesis of Fused 2-Thiouracils: Dipyrimidinopyridine, Pyrazolopyrimidine and Pyridazinopyrimidines. Bull. Kor. Chem. Soc. 2003; 24: 1429-32.		

UNPUBLISHED PATENT APPLICATIONS				
Examiner Initials*	Cite No.†	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ⁶
	41.	GIRARDET, et al. US Patent Application No. 11/661,079, entitled "S-triazolyl alpha-mercaptopacetanilides as inhibitors of HIV reverse transcriptase," filed February 23, 2007. (WSGR Reference No. 18545-719.831)		

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. †Applicant's unique citation designation number (optional). See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ‡Rater Office that issued the document, by the two-letter code (WIPO Standard ST. 3). *For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. †Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST 16 if possible. ‡Applicant to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.58. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing the burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.